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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,180	01/18/2007	Bruno Balay	0512-1319	5568

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YOUNG & THOMPSON  
209 Madison Street  
Suite 500  
Alexandria, VA 22314

EXAMINER
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HOBAN, MELISSA A

ART UNIT	PAPER NUMBER
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3738

NOTIFICATION DATE	DELIVERY MODE
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06/07/2011

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/566,180	<b>Applicant(s)</b> BALAY ET AL.	
	<b>Examiner</b> MELISSA HOBAN	<b>Art Unit</b> 3738	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2011.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 18-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 18-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/28/2011 has been entered. Claims 1-13 and 18-24 are currently pending in this application.

2. The previous objection to claim 24 is withdrawn in light of applicant's amendments. The previous rejection under 35 USC 112, 2<sup>nd</sup> is also withdrawn in light of applicant's amendments.

### ***Response to Arguments***

3. Applicant's arguments with respect to the newly amended claims have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-13 and 18-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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6. Claims 1 and 18 recite the limitation “a coating carried by the cup, said coating facilitating osteointegration, or a selective calcium hydroxyapatite coating” in lines 9-10 and line 9, respectively. This limitation appears to be an incomplete thought. It is unclear whether the coating required by the claim must be a selective calcium hydroxyapatite coating.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

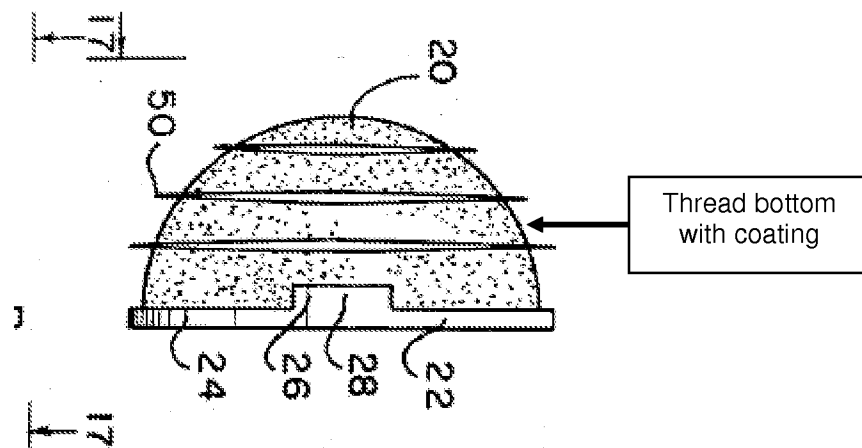
8. Claims 1, 2, 5, 13, 18, 20, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 3,840,904 to Tronzo (Tronzo).

Regarding at least claims 1 and 18

Tronzo teaches an acetabular cup prosthesis which has an outer surface having a porous coating and also blades (abstract). The cup (screw cup; 20) is smooth on the inside and preferably receives a liner (articular insert; 22) (col. 2, lines 36-41). The blades are either circular around the cup parallel to the diameter or perpendicular to the diameter or at any angle between these. On the outside of the cup, a porous composition (coating) may be molded on with a view to aiding bone growth to interlock with the cup (col. 2, lines 57-60). The blades may or may not be coated in contrast to the main cup (col. 2, lines 30-35). Figs. 14 and 15 show a form of the invention which has blades (50) on the outside of the cup, the blades extending in a circular direction

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parallel to the diameter (col. 3, lines 45-49). The circular direction of the blades are construed by the examiner to meet the limitation of screwing means/threads at a periphery and/or in a tropical/equatorial zone of the cup, intended to be introduced into bone material of the acetabulum during a screwing action, as claimed by applicant. It is also clear from figs. 14 and 15 that Tronzo meets the limitation that the coating is thick on convex portions of an outer surface of the cup (20), including on thread bottoms of said screwing means and the coating has a lesser thickness, or is even absent, on screw reliefs (blades in the circular direction without coating; 50) of said screwing means, as claimed by applicant. See annotated figure below.



With regard to the functional language used throughout the claims, the examiner notes that the device of Tronzo is fully capable of meeting the claimed functions and that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).  
Regarding at least claims 2, 5, 13, 20, and 23

As explained above, the blades (screw reliefs; 50) of figs. 14 and 15 taught by Tronzo are construed as not having any coating. The examiner takes the position that at least the sharpness of the blade (screw reliefs; 50) meets the limitation of having a rough surface, as claimed by applicant. It can also be seen from these figs 14 and 15 of Tronzo that the screwing means has a spherical threading which appears to be of constant pitch, as claimed by applicant. Tronzo further appears to meet the limitation of having a regular threading pitch, as claimed by applicant, since the definition of regular is: conforming to a standard or pattern, which Tronzo's threading pitch clearly does.

Tronzo also teaches that the porous material should be at least 100 microns thick, preferably at least 1/16 inch thick and most desirably at least 1/8 inch thick (col. 3, lines 54 and col. 4, lines 1-3), thereby meeting the limitation that the thick coating has a thickness from 100 to 200 micrometers, as claimed.

With regard to the functional language used throughout the claims, the examiner notes that the device of Tronzo is fully capable of meeting the claimed functions and that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 3, 4, 19, 21, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tronzo, as evidenced by US Patent Application Publication No. 2005/0267585 A1 to Sidebotham (Sidebotham).

Regarding at least claims 3, 19, and 21

Tronzo teaches the invention substantially as claimed according to claims 1, 2, and 20. However, Tronzo does not explicitly teach a thickness of the thick coating of an order of 150 +/- 35 micrometers. Tronzo also does not explicitly teach a selective calcium hydroxyapatite coating.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the thickness taught by Tronzo to specify that the coating is of an order of 150 +/- 35 micrometers, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Further, it would have been obvious to specify this range of thickness since this range of thickness is well known in the art for coatings on acetabular shells, as evidenced by Sidebotham (paragraph 0038, lines 1-7), particularly in view of the lack of any disclosed criticality of the claimed limitations (see page 3 of applicant's specification which clearly states that these thicknesses are not limiting and that they are dependent on the type and quality of the osteointegrating coating).

It also would have been obvious to one having ordinary skill in the art at the time of the invention to specify that the porous composition taught by Tronzo is a selective calcium hydroxyapatite coating, since this type of coating is well known in the art as a

porous composite and has been used in combination with implants, in order to allow for bone-growth resulting in firm attachment.

Regarding at least claims 4 and 22

Tronzo teaches the invention substantially as claimed according to claims 1 and 18. As explained above, Tronzo teaches that the blades (screw reliefs; 50) may or may not be coated in contrast to the main cup (col. 2, lines 30-35). However, Tronzo does not teach an order of coating of 50 +/- 30 micrometers on the screw reliefs.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the invention of Tronzo to include that the coating of the blades is of an order of 50 +/- 30 micrometers, since a portion of the porous composite having a thickness, for example, of about 100 micrometers, as taught by Tronzo (col. 4, line 1), may be inadvertently sprayed onto the blades resulting in a thickness on the blades of less than 100 micrometers, thereby potentially meeting the claimed range, particularly in view of the lack of any disclosed criticality of the claimed limitation (see claims 1 and 18, which state that the coating may be absent on the screw reliefs). It also would have been obvious, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

11. Claims 6, 7, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tronzo in view of US Patent No. 4,883,491 to Mallory et al. (Mallory).

Tronzo also does not teach a thread pitch ratio, an asymmetrical cross-section of the threads, or successive threads.



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Regarding at least claims 6 and 24

Tronzo teaches the invention substantially as claimed according to claims 1 and 18. However, Tronzo does not explicitly teach that the screw reliefs are arranged to apply a self-tapping cutting effect during the screwing action and effect compression of the bone material.

Mallory teaches a porous-coated, threaded acetabular cup (screw cup; 10) including a self-tapping screw thread (screwing means; 16) (col. 2, lines 46-56 and col. 3, lines 36-38). The thread (16) is formed on the outer surface of the body (18) by milling the surface and is preferably a spherical thread that includes leading edges (30) which are sufficiently sharp for the thread to be self-tapping (col. 3, lines 55-61 and fig. 1).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the screw cup of Tronzo to include a self-tapping cutting effect during the screwing action and effect compression of the bone material, in order to provide an ability to advance when turned, while creating its own thread, particularly since these screw types are well known in the art.

With regard to the functional language used throughout the claims, the examiner notes that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Regarding at least claim 7

Tronzo in view of Mallory teaches the invention substantially as claimed according to claim 6. Though Tronzo in view of Mallory does not appear to explicitly teach a proportion of thread width relative to a thread pitch from 0.2 to 0.5, the examiner takes the position that it would have been obvious to include such proportions, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. It also would have been obvious particularly in view of the lack of any disclosed criticality of the claimed limitation (see page 4 of applicant's specification which implies that this proportion is not material to the patentability of the invention).

12. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tronzo in view of Mallory, as evidenced by US Patent No. 5,443,520 to Zweymuller et al. (Zweymuller).

Tronzo teaches the invention substantially as claimed according to claim 1. However, Tronzo does not teach an asymmetrical cross-section of the threads in a diameter plane.

As explained above, Mallory teaches that the thread (16) is formed on the outer surface of the body (18) by milling the surface and is preferably a spherical thread that includes leading edges (30) which are sufficiently sharp for the thread to be self-tapping (col. 3, lines 55-61 and fig. 1). Though Mallory does not appear to explicitly teach angles of the threads with respect to the outer surface of the cup, Mallory does teach that the cup includes a self-tapping screw thread having a cross-section which appears to be

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asymmetrical in a diametral plane, at least to the same extent applicant's is, with a smaller angle at the polar side of the thread and a greater angle at an equatorial side (fig. 3).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the invention of Tronzo in view of Mallory to include specifics about the threads, such as angles, in order to include threads having a size, thickness, and height adapted to the size of the socket component for use so that the operator, during surgery, can select a cup matched to the quality of bone material in the pelvic region, as evidenced by Zweymuller (col. 6, lines 15-26). It also would have been obvious to specify the angles of the threads on the polar side and on the equatorial side, particularly in view of the absence of any disclosed criticality of the claimed limitations. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

13. Claims 9-10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tronzo in view of US Patent No. 5,147,407 to Tager (Tager).

Tronzo teaches the invention substantially as claimed according to claim 1. However, Tronzo does not explicitly teach that the crests of threads are relieved or that the leading edge is inclined.

Tager teaches a prosthetic cup member having an outer surface with coaxial threads interrupted by grooves extending transversely to the thread. The threads are self-tapping threads and are formed to permit the threaded outer shell to be screwed

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into the bone (abstract). Tager further teaches that openings (inclined grooves; 11) are milled at an angle with respect to the axis and at an angle with respect to the radius, i.e. the walls of the openings are inclined towards the rotational direction of outer shell (10) (col. 3, lines 1-9). The discrete thread portions (12) form a plurality of rows (zones; 13) at an angle to the axis of outer shell (10) between openings (11). Since the device taught by Tager is made in the same way as applicant's, it is inherent that it also includes crests with leading edges of threads that are radially higher than the remainder of the crest, and which leading edges are themselves inclined by being formed by a milling pass, as claimed by applicant.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the invention of Tronzo to include crests of threads that are relieved or that the leading edge is inclined in order to facilitate insertion of the cup and improve its anchoring after emplacement, as taught by Tager (col. 2, lines 14-20).

### ***Conclusion***

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The reference to Sidebotham (US Patent Application Publication No. 2005/0267585 A1) discloses acetabular cups having a porous sintered coating on the order of 250 +/- 50 micrometers on the outer surface for maintaining intimate contact encouraging bone ingrowth. The coating appears to be located on the convex surface of the cup, including on thread bottoms (fig. 2).

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA HOBAN whose telephone number is

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(571)270-5785. The examiner can normally be reached on Monday-Friday 8:00AM-5:00PM EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571)272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MH

/BRUCE E SNOW/  
Primary Examiner, Art Unit 3738